

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION**

UNITED STATES OF AMERICA
ex rel. Brook Jackson,

Plaintiff,

v.

**VENTAVIA RESEARCH GROUP, LLC;
PFIZER INC.; ICON PLC,**

Defendants.

CASE NO. 1:21-CV-00008-MJT

ORAL ARGUMENT REQUESTED

**VENTAVIA RESEARCH GROUP, LLC'S REPLY BRIEF IN SUPPORT OF ITS
MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT**

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INTRODUCTION

Instead of trying to fix the legal deficiencies that led to this Court’s initial dismissal order, Relator’s opposition suggests she has all but given up on any aspect of this litigation that does not advance her public-relations agenda. The opposition makes a lot of sweeping (and wrong) assertions about how Pfizer supposedly tricked the government into approving a “dangerous, ineffective drug.” (*See, e.g.*, Dkt. 127 at 1-3.) But it doesn’t say nearly as much when it comes to the nitty-gritty work of supporting all the essential elements of Relator’s liability theories.

Take, for instance, the proximate-cause element of Relator’s indirect FCA claims. (*See* Dkt. 121 at 4-8.) That element is critically important as a legal matter because a relator must allege viable FCA claims against every defendant; it cannot simply lump them all together. (*Id.* at 4, citing cases.) Ventavia made that point in the first section of its motion to dismiss and explained why the Second Amended Complaint does not allege that Ventavia *itself* violated the FCA by causing the submission of false claims. Yet Relator offers no response to that dismissal argument. None. Whatever the reason for that choice, Relator’s lack of response alone warrants dismissal of Count I—her only remaining merits claim (*see* Dkt. 127 at 3)—as to Ventavia.

The responses she does offer fare no better. Relator says she has alleged viable causes of action for retaliation under federal and state law, but she is wrong. The Court already dismissed the FCA retaliation claim once—because Relator’s alleged reports about regulatory compliance are not protected activity under settled Fifth Circuit precedent—and nothing has changed there. Relator’s new state-law cause of action fails as a matter of straightforward statutory text. And as if to prove the point, Relator now asks for *another* opportunity to replead in hopes of finding a viable retaliation theory. There is no such theory, but the Court should not indulge the exercise. The law is clear that a plaintiff should not be permitted to drag a lawsuit out through seriatim assertions of

endless legal theories. The time has come to put this case to bed. Ventavia respectfully asks the Court to do just that by dismissing all of Relator's remaining counts against it with prejudice.

ARGUMENTS IN REPLY

I. Relator makes no attempt to explain how Ventavia itself violated the FCA.

The first order of business is to dismiss Count I as to Ventavia. In their motions, Pfizer and ICON address numerous reasons why that claim fails as a matter of law and should be dismissed as to all defendants. Ventavia adopts and incorporates by reference the arguments addressed in their reply briefs as well. But regardless of how the Court resolves those issues, Count I fails as to Ventavia because Relator has not alleged that it proximately caused the submission of false claims.

Not much needs to be said here because, again, Relator says nothing about this argument in her opposition. It's not just that Relator's causation arguments are weak—they're not there. She says nothing about the legal standards for her indirect FCA theories, and thus does not contest her obligation to show that Ventavia proximately caused the submission of false claims. (Dkt. 121 at 4-8.) Nor does Relator argue that her pleading connects those proximate-cause dots—because it does not. (*See id.* at 6-8.) In one drive-by sentence, Relator suggests that Ventavia "caus[ed] submission of unreliable data to the FDA." (Dkt. 127 at 3.) That unsupported conclusion doesn't address any of the fatal flaws raised in Ventavia's motion. (Dkt. 121 at 7.) If Relator won't bother to explain why her indirect FCA theories should survive, the Court should not do the work for her; Count I fails for that reason alone. *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1010 (5th Cir. 2023) ("[W]ell-settled precedent instructs that a party abandons a claim by failing to defend it in response to motions to dismiss and other dispositive pleadings.").

Other portions of the opposition serve only to highlight the weaknesses in Relator's causal chain. Relator has previously pointed to the study "endpoint" as indicating that Ventavia's data

could have affected the FDA’s decision-making, and she comes back to that point in her opposition. (Dkt. 121 at 7-8; Dkt. 127 at 16-17.) But Relator’s fuzzy math doesn’t show anything; it certainly does not show that the Ventavia data proximately caused the FDA to approve the vaccine (as she would have to do). Instead, her discussion consists mostly of hypothetical musings about how some unidentified number of errors “*could* result in large changes in the final estimate of vaccine efficacy and safety.” (Dkt. 127 at 16-17, emphasis added.) That vague claim accomplishes nothing, and it’s not connected to Ventavia in any event. Neither are the two people she claims were injured by the vaccine—because Relator judicially admitted those people were *not* in the Ventavia data. (*Id.* at 7, 17.) More broadly, there is no well-pleaded allegation that the removal of those two people from the trial data would have changed the FDA’s approval decision. And, again, the FDA has said the opposite. (Dkt. 70 at 11-12.)

The problems go on, but there is no sense in belaboring this unrebutted point. Count I must be dismissed as to Ventavia because Relator has not sufficiently alleged that it violated the FCA.

II. Relator’s attempts to justify her retaliation claims fall short as a matter of law.

The result is the same for Counts V and VI alleging retaliation. Though Relator does attempt to defend these claims, her responses are legally meritless. And she certainly should not be given another opportunity to try asserting another misguided retaliation theory.

A. Nothing has changed about the already-dismissed FCA retaliation claim.

Relator first says she has alleged a viable claim for retaliation under the FCA. (Dkt. 127 at 24.) This Court already held otherwise, correctly finding that Relator has no FCA retaliation claim because, among other reasons, she did not engage in “protected activity” under the FCA. (Dkt. 96 at 46, 48.) Relator now says that conclusion was wrong, but neither argument holds up.

Her first argument misses the point entirely. Relator says her FCA retaliation claim should be revived because she “now pleads a viable theory of False Claims Act violations,” through her fraud-in-the-inducement theory. (Dkt. 127 at 24.) That’s not a viable theory at all, as Pfizer explains. But that’s also not legally relevant, because the retaliation provision isn’t concerned with the *validity* of the FCA theory—the question is whether Relator internally reported concerns about false claims for government payment, as opposed to mere regulatory violations. *See United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App’x 366, 372 (5th Cir. 2011). Relator’s complaints were on the wrong side of that line, as this Court properly held. (*See* Dkt. 96 at 46; Dkt. 53 at 21-23.) Nothing has changed about Relator’s internal reports, so the result shouldn’t either.

Relator next argues that she had “a good faith belief” she was stopping an FCA violation and that her motivations cannot be assessed at the motion-to-dismiss phase. (Dkt. 127 at 24.) Those arguments are also irrelevant (and wrong). In the Fifth Circuit, it makes no difference whether the relator believed there was fraud on the government. The question is whether she *reported* it to her employer: without such a report, there can be no retaliation as a matter of fact or law.¹ And that protected-activity element is ripe for dismissal on the pleadings if the plaintiff fails to make the required allegations, as this Court did in the Dismissal Order and as Judge Crone did in *United States ex rel. Reddell v. DynCorp Int’l, LLC*, 2019 WL 12875471, at *16 (E.D. Tex. Mar. 20, 2019).

Finally, Relator still has not cured the other independent flaw in her FCA retaliation theory: her failure to allege that Ventavia *knew* she was engaged in protected activity. (Dkt. 96 at 48.) This Court properly found that Relator never alleged this essential element, and she still didn’t

¹ If there is no clear report addressed to fraud against the government, the Fifth Circuit has explained that the employer “could not possess the retaliatory intent necessary to establish a violation of § 3730(h).” *Patton*, 418 F. App’x at 372 (quotations omitted).

do so in the Second Amended Complaint. A few conclusory sentences in her opposition (Dkt. 127 at 24) don't fix that. *See, e.g., Energy Coal S.P.A. v. CITGO Pet. Corp.*, 836 F.3d 457, 462 n.4 (5th Cir. 2016) (“[T]he complaint may not be amended by the briefs in opposition to a motion to dismiss.”) (quotations and citations omitted). Relator also continues to ignore the fact that her alleged phone call to the FDA is irrelevant to Ventavia's knowledge because she never alleges that it knew about that alleged communication prior to terminating her (and it didn't). (*See* Dkt. 127 at 27-28.) Nothing has changed with respect to the two independent bases on which this Court dismissed Relator's FCA retaliation claim. This claim must be dismissed, again.

B. Relator's state-law retaliation claim fails under the plain statutory text.

The Court should also dismiss Relator's new state-law retaliation claim under Texas Health and Safety Code § 161.134 because that provision does not apply here as a matter of law. (Dkt. 121 at 9-13.) Relator's statutory arguments to the contrary fix nothing.

Relator first argues, because she must, that Ventavia is the kind of healthcare facility covered by Section 161.134. (Dkt. 127 at 26.) She says that Ventavia is a “treatment facility” because that term should encompass “any facility where medical care of some type is provided.” (*See id.*) But that's not at all what the statute says. The term “treatment facility” is expressly defined by reference to Section 464.001, which lists facilities like hospitals, outpatient facilities, halfway houses, and “any other facility that offers or purports to offer treatment.” TEX. HEALTH & SAFETY CODE § 464.001(5)(A-L). Treatment is defined as “a planned, structured, and organized program designed to initiate and promote a person's chemical-free status or to maintain the person free of illegal drugs.” *Id.* § 464.001(4). Under those definitions, Ventavia is not a treatment facility because it does not provide programs that promote chemical- or drug-free status.

Relator's response to those definitions is as desperate as it is wrong: she says Section 161 didn't incorporate the definition of "treatment," only "treatment facility." (Dkt. 127 at 26.) But the former is part of the latter—it's the first word in the term. Plus, as a matter of grammar and ordinary usage, the meaning of "treatment" necessarily modifies what qualifies as a "treatment facility." In short, Relator cannot escape the chemical-dependency limitation that the Legislature applied in defining treatment facilities, and she does not allege or argue that Ventavia meets that limitation. It undisputedly does not provide chemical- or drug-free treatment programs.

Though the statutory text alone defeats Relator's retaliation claim, her arguments are also inconsistent with existing caselaw, as she acknowledges. (Dkt. 127 at 26.) At least two cases have held that the term "treatment facility" in Section 161.134 is plainly limited to those that provide some form of chemical dependency or addiction treatment programs. *Nichols v. HealthSouth Corp.*, 2001 WL 1081288, at *3-4 (N.D. Tex. Sept. 12, 2001); *Barron v. Cook Children's Health Care Sys.*, 218 S.W.3d 806, 809 (Tex. App.—Fort Worth 2007, no pet.).

Relator says "there is good reason to doubt those decisions" but cannot support that claim. (Dkt. 127 at 26.) Her argument appears to be that "treatment facility" should not be limited to addiction or recovery services because the definition in Section 464.001 extends to broader facilities like hospitals and health maintenance organizations. (*See id.* at 26-27.) But those facilities only qualify as treatment facilities when and to the extent they are "offer[ing] or purport[ing] to offer treatment," as the statutory catch-all makes clear. TEX. HEALTH & SAFETY CODE § 464.001(5)(L) (emphasis added). That's exactly what the two courts addressed above determined. *See Nichols*, 2001 WL 1081288 at *4; *Barron*, 218 S.W.3d at 809-10. And that reading of the statute is particularly appropriate in light of the purpose of Section 161.134, which—as Ventavia addressed

in its motion—was designed to address misconduct against patients receiving chemical dependency, mental health, or rehabilitation services. (Dkt. 121 at 10.) Relator ignores that inconvenient fact as well. But there is no basis to ignore the text of the statute. Ventavia is not a “treatment facility,” so Relator has no retaliation claim under Section 161.134.

Yet there is more. Relator’s retaliation claim also fails for the independent reason that she has not alleged the kind of “violation of law” required to trigger Section 161.134(a). As Ventavia explained, that term applies only to a few narrow categories of state-law violations—and Relator has alleged none. (Dkt. 121 at 11-12.) Her response quibbles on this statutory interpretation, arguing briefly that “there is no support for that argument.” (Dkt. 127 at 28.) The support comes from the text of the statute and from a settled canon of construction recognized by the Supreme Court and a well-regarded usage manual, which Relator does not address. (Dkt. 121 at 11.)

Nor does Relator provide any support for her alternative reading that Section 161.134 applies to violations of federal law. The only case she cites for this point (*Smart*) merely mentions the statutory language in passing and says nothing about extending it to violations of federal law. 626 F. Supp. 2d 647, 657 (S.D. Tex. 2009). In any event, the only reported “violation of law” that Relator now points to as supporting her state-law retaliation claim is the alleged violations of FDA regulations. (Dkt. 127 at 27-28.) That’s a problem because it’s not alleged that way in her complaint: the Second Amended Complaint says this claim is based on alleged violations of Federal Acquisition Regulations. (Dkt. 118 ¶ 343.) Again, Relator cannot change theories through her motion-to-dismiss response. *Energy Coal S.P.A.*, 836 F.3d at 462 n.4. But regardless, her FDA theory fails for the same reasons and does not support her state-law retaliation claim.

Finally, Relator did not bother to address Ventavia’s alternative argument that this Court

should decline to exercise supplemental jurisdiction in the event the state-law retaliation claim somehow survives. (Dkt. 121 at 13-14.) But Relator cannot wish that argument away. If the Court dismisses the FCA claims—and it should—the law is clear that the pendent state-law claims should be dismissed as well, regardless of merit. (*See id.*) So, this unrebutted argument provides yet another independent basis for dismissing Relator’s retaliation claim under Section 161.134.

C. Relator should not be permitted another amendment.

In one final attempt to drag this case out further, Relator requests leave to file *another* amended complaint, both for the specific purpose of pleading a new common-law claim for wrongful termination (Dkt. 127 at 28) and for the more general purpose of curing any further deficiencies (*id.* at 32). Both requests should be rejected with prejudice.

Relator has had more than enough opportunity to plead a viable claim if she has one. She filed her original complaint three years ago (in January 2021) and her first amendment in February 2022. (Dkt. 2, 17.) After this Court properly dismissed her claims—and after Relator created a procedural mess of post-judgment filings—the Court generously granted her leave to amend. (Dkt. 108 at 2-3.) Even then, the amended complaint that Relator ultimately filed expands on the one attached to her motion for leave, meaning she has now effectively had three bites at the amendment apple (in addition to her original complaint). (*Compare* Dkt. 99, Ex. 2 *with* Dkt. 118.) At every step of that process, Relator could have alleged the wrongful termination claim she now wants to try. Indeed, Relator *admits* it is based on the same alleged facts she had all along. (Dkt. 127 at 28.)

The Court should therefore reject Relator’s repleading request because of her undue delay and dilatory motive, as other courts have done when a plaintiff “knew the ‘basic facts’ supporting its new claims ‘all along’” and yet “‘waited to assert its [new] claims in a last ditch effort’” to avoid dismissal. *C3PO Int’l, Ltd. v. DynCorp Int’l, L.L.C.*, 663 F. App’x 311, 314 (5th Cir. 2016)

(affirming denial of leave to amend); *see also Schiller v. Physicians Res. Grp. Inc.*, 342 F.3d 563, 566–67 (5th Cir. 2003) (affirming denial of leave to amend after the district court found that the “plaintiff has had fair opportunity to make his case” and an amendment would “be an inefficient use of the parties’ and the court’s resources, would cause unnecessary and undue delay, and would be futile”) (quotations and citations omitted); *Allen v. Walmart Stores L.L.C.*, 907 F.3d 170, 186 (5th Cir. 2018) (finding undue delay when plaintiff waited to seek leave to amend until after the court ruled on the defendant’s motion to dismiss).

The Fifth Circuit has often noted that “[a] busy district court need not allow itself to be imposed upon by the presentation of theories seriatim,” *i.e.*, when a litigant “tr[ies] a different tack” only after other theories have failed. *See Freeman v. Cont’l Gin Co.*, 381 F.2d 459, 469 (5th Cir. 1967); *S. Constructors Grp., Inc. v. Dynalectric Co.*, 2 F.3d 606, 612 (5th Cir. 1993). Indeed, “[m]uch of the value” of dispositive motion procedures “would be dissipated if a party were free to rely on one theory in an attempt to defect a motion...and then, should that theory prove unsound, come back long thereafter and fight on the basis of some other theory.” *See Freeman*, 381 at 469–70. “Liberality in amendment is important to assure a party a fair opportunity to present his claims and defenses, but ‘equal attention should be given to the proposition that there must be an end finally to a particular litigation.’” *Id.* at 469. This is just such a case. The Court has given Relator every reasonable opportunity to plead a viable claim. There is no basis to allow another.² It is time for this case to come to an end.

² That basis certainly doesn’t come from Relator’s more general request for leave to amend if “the Court find[s] any deficiencies.” (Dkt. 127 at 32.) The Fifth Circuit has affirmed the denial of leave to amend when a plaintiff “tack[s] on a general curative amendment request to the end of their response in opposition to the defendants’ motion to dismiss.” *Goldstein v. MCI WorldCom*, 340 F.3d 238, 254–55 (5th Cir. 2003). That’s exactly what Relator did.

CONCLUSION AND PRAYER

Ventavia respectfully requests that the Court grant its Motion to Dismiss, along with the others, and dismiss with prejudice all of the claims asserted against it in Relator's Second Amended Complaint. Ventavia also requests that the Court grant any other relief to which it may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record on January 19, 2024, pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Taryn M. McDonald

Taryn M. McDonald